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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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EXAMINER

RAO, MANJUNATH N

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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1652

DATE MAILED: 05/05/2004

8

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/731,632

Applicant(s)

CROMLISH ET AL.

Examiner

Manjunath N. Rao, Ph.D.

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 February 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 November 2000 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Reissue Application

Claims 1-27 are currently pending in this re-issue application.

Applicant is reminded of the continuing obligation under 37 CFR 1.178(b), to timely apprise the Office of any prior or concurrent proceeding in which Patent No. 5,543,297 is or was involved. These proceedings would include interferences, reissues, reexaminations, and litigation.

Applicant is further reminded of the continuing obligation under 37 CFR 1.56, to timely apprise the Office of any information which is material to patentability of the claims under consideration in this reissue application.

These obligations rest with each individual associated with the filing and prosecution of this application for reissue. See also MPEP §§ 1404, 1442.01 and 1442.04.

Drawings

Drawings submitted in this application are accepted by the Examiner for examination purposes only.

Specification

The specification is objected due to the following reason/s; Applicants do not provide the specification in a double column format as required for re-issue applications. Applicant is notified that any subsequent amendment to the specification and/or claims must comply with 37 CFR 1.173(b).

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Applicants need to amend the specification by providing the new address of ATCC wherever the previous old address is recited in the specification. Correction is required.

Sequence Compliance

Applicant is required to comply with the sequence rules by inserting the sequence identification numbers of all sequences recited within the claims and/or specification. It is particularly noted that applicants have neither requested the transfer of the electronic form of the sequence information from the parent application to the instant re-issue application nor filed an electronic form of the sequence information to the STIC library with respect to the instant application. See particularly 37 CFR 1.821(d).

Applicant is notified that any subsequent amendment to the specification and/or claims must comply with 37 CFR 1.173(b).

Information Disclosure Statement

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered. Applicant is urged to provide the references on Form 1449. Examiner urges applicants to provide a Form 1449 listing all references cited on the face of the patent or at the time of previous allowance.

Applicant is notified that any subsequent amendment to the specification and/or claims must comply with 37 CFR 1.173(b).

Submission of the Original Patent

Applicants have not submitted the original patent. The original patent, or a statement as to loss or inaccessibility of the original patent, must be received before this reissue application can be allowed. See 37 CFR 1.178.

Defective Oath/declaration

The reissue oath/declaration filed with this application is defective (see 37 CFR 1.175 and MPEP § 1414) because of the following:

1) The error specified is not the one that is corrected. Applicants have indicated that claims 20 and 21 are in error because they do not have antecedence. However, said error has not been addressed and remains in the claims.

2) Applicant fails to provide the residential address/ mailing address of inventors 3 through 6.

Claims 1-27 are rejected as being based upon a defective reissue Declaration under 35 U.S.C. 251 as set forth above. See 37 CFR 1.175.

The nature of the defect(s) in the Declaration is set forth in the discussion above in this Office action. Applicant is notified that any subsequent amendment to the specification and/or claims must comply with 37 CFR 1.173(b).

Claim Objections

Claims 17-19, 22-25 are objected to because of the following informalities: Claims 17-19, 22-25 present SEQ ID NO with a colon mark (:) after the specific number which is unnecessary. Examiner urges applicants to remove the colon mark. Appropriate correction is required.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 18 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claim 18 is drawn to a human cyclooxygenase-2 (shown in figure 1) which reads on a product of nature. Amending the claim to recite "An isolated cyclooxygenase.." to show the hand of man would overcome the above rejection.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 20-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 20-21 recite the limitation "A system" in line 1. There is insufficient antecedent basis for this limitation in the claim.

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Claims 17 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 17 drawn to a human COX-2 cDNA improperly depends from claim 15 which is directed to an assay which neither makes nor uses the cDNA claimed in claim 17. Claim is also rejected because it lacks antecedence to claim 15. Correction is required. However, Examiner warns applicant that if claim 17 is amended to depend from claim 16 as it should, then newly added claim 22 becomes a duplicate claim of claim 17 and such duplicate claims will not be allowed. Please MPEP 706.03(k).

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 16-25 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 16-25 are directed to humancyclooxygenase-2 cDNA with SEQ ID NO:11 and purified, recombinant or isolated human cyclooxygenase-2 polypeptide having an amino acid sequence SEQ ID NO:10. Claims 16-25 are rejected under this section of 35 USC 112 because the claims are directed to a genus of polypeptides derived from humans that have not been disclosed in the specification. The examiner maintains the position that the single representative disclosed species, i.e., the polypeptide with SEQ ID NO:10 and the polynucleotide with SEQ ID NO:11, fails to represent the entire genus of claimed human cyclooxygenase-2 polypeptides (underline added for emphasis).

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The Court of Appeals for the Federal Circuit has recently held that a “written description of an invention involving a chemical genus, like a description of a chemical species, ‘requires a precise definition, such as be structure, formula [or] chemical name,’ of the claimed subject matter sufficient to distinguish it from other materials.” *University of California v. Eli Lilly and Co.* 43 USPQ2d 1398 (Fed. Cir. 1997), quoting *Fiers v. Revel* , 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) (bracketed material in original). To fully describe a genus of genetic materials, which is a chemical compound, applicants must (1) fully describe at least one species of the claimed genus sufficient to represent said genus whereby a skilled artisan, in view of the prior art, could predict the structure of other species encompassed by the claimed genus and (2) identify the common characteristics of the claimed molecules, e.g., structure, physical and/or chemical characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or a combination of these. In the instant specification, a single human COX-2 polypeptide is described as SEQ ID NO:10, (which is encoded by SEQ ID NO:11) having prostaglandin synthase activity. This description also adequately describes a genus, within the sequence identity limitation of the instant claims, of polypeptides having this particular function. Those sequences that are "human" are a subset of this genus of polypeptides/polynucleotides having greater than 95% amino acid sequence identity to SEQ ID NO:10/11 and having said activity. The specification fails to define those structural features of SEQ ID NO:10/11 that are commonly possessed by members of the genus that distinguish them from other “non-human” polypeptides. Thus, one skilled in the art cannot visualize or recognize the identity of the members of the genus. As such, this single representative species does not adequately describe this subset according to its structure so that one of skill in the art can visualize and distinguish those amino acid sequences that are human, particularly in view of the larger genus that includes both human and non-human sequences. Therefore, the instant claims are not adequately described.

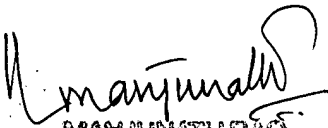
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Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

Conclusion

None of the claims are allowable.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Manjunath N. Rao, Ph.D. whose telephone number is 571-272-0939. The Examiner can normally be reached on 7.00 a.m. to 3.30 p.m. If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Ponnathapura Achutamurthy can be reached on 571-272-0928. The fax phone numbers for the organization where this application or proceeding is assigned is 703-872-9306 for regular communications and for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.


MANJUNATH RAO
PATENT EXAMINER
Manjunath N. Rao
April 30, 2004